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ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE FIRST NAMED INVENTOR APPLICATION NO. 209334USOPCT 1165 06/12/2001 Kazuhiko Take 09/857,869 **EXAMINER** 22850 02/05/2004 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. BERNHARDT, EMILY B 1940 DUKE STREET ART UNIT PAPER NUMBER ALEXANDRIA, VA 22314 1624

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)
	09/857,869	TAKE ET AL.
	Examin r	Art Unit
	Emily Bernhardt	1624
The MAILING DATE of this communication app	ars on the cover shet with the c	orrespondence address
THE REPLY FILED 13 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.		
PERIOD FOR REPLY [check either a) or b)]		
a) The period for reply expiresmonths from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).  Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
<ul> <li>1. A Notice of Appeal was filed on 13 August 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.</li> <li>2. The proposed amendment(s) will not be entered because:</li> </ul>		
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);		
(a) ☐ they raise hew issues that would require further consideration and/or search (see NOTE below);		
(c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the		
issues for appeal; and/or		
<ul><li>(d) they present additional claims without canceling a corresponding number of finally rejected claims.</li><li>NOTE:</li></ul>		
3. Applicant's reply has overcome the following rejection(s): See attached response.		
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).		
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because:		
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.		
7. ☑ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.		
The status of the claim(s) is (or will be) as follows:		
Claim(s) allowed:		
Claim(s) objected to:		
Claim(s) rejected: <u>11-18</u> .		
Claim(s) withdrawn from consideration:		
8. ☐ The drawing correction filed on is a) ☐ approved or b) ☐ disapproved by the Examiner.		
9. Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s)		
10.⊠ Other: <i>PTO-413</i>		
		Emily Bernhardt Primary Examiner Art Unit: 1624

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and the

The after final amendment will be entered since it removes the 112 rejection for claim 16. However, the newly submitted declaration filed 1/13/04 directed to overcoming the Miyake reference will not be considered since the declaration was filed after a final rejection as well as a Notice of Appeal and applicants have not shown good and sufficient reasons why it was not earlier presented as required under 37 CFR 1.195. Applicants also mention a 3<sup>rd</sup> declaration filed to address the Matsuo rejection which is not seen in the file but again would not be considered since such would require more than a cursory review of the new data submitted in determining its effectiveness in overcoming the 103 rejection. This Declaration is discussed on p.10 of applicants' AF response.

Thus both 103 rejections as well as corresponding obviousness double patenting rejections set forth in the final rejection would remain. All of the deficiencies previously pointed out in the "first" Matsuo Declaration (filed 1/13/03) would still remain notwithstanding applicants' remarks made in the AF response regarding no need for asserting superior and unexpected results that are of both practical and statistical significance. Regarding the former it is clearly stated in the MPEP 716.02 (b) that it is applicants' burden to establish superior and unexpected results. Mere attorney's arguments do not suffice as emphasized in Gelles. For showing statistical significance see in addition to Gelles, Ex parte

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Quadranti 25 USPQ 2d 1071 (affirming the examiner in that case while citing Kollman) which emphasized that the facts (i.e. data, test results) in each case determine legal outcome. While the same assay as described in the specification was used according to declarant in the 1<sup>st</sup> Declaration, and stated by applicants in their AF response there is no discussion whatsoever of any IC 50 values measured for compounds described as being tested. As stated in previous action there may be as much variability among instant compounds than those closest to the prior art, Matsuo.

Applicants' statement regarding common ownership with US'357 and copending 09/446145 is acknowledged.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (703)308-4714.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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F Bemhardt
Emily Bernhardt
Primary Examiner
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